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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,154	08/18/2003	Jeffrey E. Stahmann	GUID.103PA	3600

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EXAMINER	
ALTER, ALYSSA M	

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 11/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/643,154	STAHMANN ET AL.	
	Examiner	Art Unit	
	Alyssa M. Alter	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-48 and 80-100* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-48 and 80-100* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 August 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/13/04 & 3/3/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of the restriction requirement in the reply filed on August 15, 2005 is acknowledged. Applicant's election with traverse of the election of species is also acknowledged. The traversal is on the ground(s) that species are not in specifically different embodiments. This is found persuasive, and thus the election of species requirement is withdrawn. The claims that are pending in this application are 1-48 and 80-100.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The examiner is unsure what the applicant it claiming, since the very conditions used to determine he predicted disorder are then verifying the prediction. Naturally the values would support this prediction.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140

F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 1-48 and 80-100 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-97 of copending Application No. 10/643,203 (US Patent Publication 20050039745 A1). Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications claim the used of providing detecting and treating disordered breathing through delivery of cardiac electrical therapy.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

2. Claims 1-48 and 80-100 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-27 and 33-96 of copending Application No. 10/642,998 (US Patent Publication 20050042589 A1) in view of Park et al. (US 6,928,324). Application No. 10/642,998 claims the Applicant's invention except for the delivery of cardiac electrical treatment. Park et al. claims to employ one or more pulse generators that are capable of generating cardiac pacing pulses, wherein the circuitry is responsive to the detected sleep apnea condition to

control the one or more pulse generators to generate cardiac pulses with a timing that tends to terminate the detected sleep apnea condition, as set forth in claim 1. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the detection device as taught by Application No. 10/642,998 to include the treatment as taught by Park et al., since such a modification would enable the patient to have treatment delivered upon the detection of an apnea event or precursor, and thus reduce the hiatus between detection and treatment.

This is a provisional obviousness-type double patenting rejection.

3. Claims 1-48 and 80-100 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-102 of copending Application No. 10/643,016 (US Patent Publication 20050043644 A1) in view of Park et al. (US 6,928,324). Application No. 10/643,016 claims the Applicant's invention except for the delivery of cardiac electrical treatment. Park et al. claims to employ one or more pulse generators that are capable of generating cardiac pacing pulses, wherein the circuitry is responsive to the detected sleep apnea condition to control the one or more pulse generators to generate cardiac pulses with a timing that tends to terminate the detected sleep apnea condition, as set forth in claim 1. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the detection device as taught by Application No. 10/643,016 to include the treatment as taught by Park et al., since such a modification would enable the patient to have treatment delivered upon the detection of an apnea event or precursor, and thus reduce the hiatus between detection and treatment.

This is a provisional obviousness-type double patenting rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-9, 14-18, 22-34, 37, 39-42, 45, 47-48, 80-83, 85-86, 88-96, 98 and 100 are rejected under 35 U.S.C. 102(e) as being anticipated by Cho et al. (US Patent Publication 20020193697 A1). Cho et al. discloses a method and apparatus for the detection and treatment of sleep respiratory events. The apparatus has an implantable first sensor for detecting of information to related to sleep apnea, a program for performing diagnostics and decision and an implantable second sensor for delivery of therapy in response to the diagnostics results.

Cho et al. further discloses on page 3, paragraph 32, that the apparatus further posses a telemetry interface 350 that can facilitate real-time access of physiological data acquired by the data acquisition controller 340, and thus allow a physician to view physiological data on a real time basis.

Figure 5 displays the plurality of various sensors that may be implement. The various sensors include an impedance sensor 510, a body movement sensor 520, an oxygen level sensor 530, and a blood pressure sensor 540. "It is noted that the sensor device 210 generally measures at least one of a variety of indices relating to sleep

apnea. The indices are typically referred as adverse events. Adverse events are the measurable events indicating abnormal sleep. Adverse events may include apnea, hypopnea (regardless the origin, type, arousals, limb movements, etc.), Cheyne-Stokes respiration ("CSR"), periodic breathing, and abnormal arousals, among other events" (page 4, paragraph 35).

The examiner considers the body movement sensor to detect the muscle system. Furthermore, since the nervous system affects the muscles, the body movement sensor also detects the nervous system. The examiner also considers the oxygen sensor to detect the blood chemistry and the blood pressure system to detect the cardiovascular system. "The impedance sensor 510 may measure, among other things, respiration and cardiac condition" (page 4, paragraph 36).

"FIG. 4, as the sensor device 210 gathers various data from the patient to detect (at 410) sleep apnea, at least one of a variety of parameters are extracted (at 420). Although not so limited, the extraction (at 420) may be performed in response to processor-based system instructions (i.e., a program) capable of being processed by the processor 310 of FIG. 3. In one embodiment, an Apnea Hypopnea Index ("AHI") (i.e., Respiration Disturbance Index ("RDI")) may be extracted. It is generally the standard in clinical practice and epidemiological studies to assess the severity of sleep-disordered breathing by combining the number of apneas and hypopneas per hour of sleep. The AHI generally refers to the total number of apneas and hypopneas divided by the total sleep time in a patient's sleep study. The AHI gives one measure of the severity of the sleep apnea"(page 5, paragraph 43). Furthermore, "the value of a

patient's AHI can be compared to certain criteria to determine the severity of sleep apnea syndrome"(page 5, paragraph 47). "Other embodiments of the present invention may require sleep therapy at a different AHI threshold or as a result of other criteria, in accordance with conventional practice", (page 6, paragraph 56), thus modifying the prediction criteria. Delivery of therapy can be issued based on the comparison of AHI criteria. Examples of such therapy are overdrive pacing or hypoglossal nerve stimulation.

"AHI may be measured upon any measure of time, for example, a nightly basis. Furthermore, the AHI for each measure of time may be stored in the memory unit 330 of the implantable medical device 220. The detecting (at 410) of sleep apnea and the extraction (at 420) of parameters over the period of time provides an effective and efficient method to detect and monitor at least one of a plurality of indices relating to a patient's sleep apnea" (page 5, paragraph 45).

Moreover, the therapy delivered will inherently be efficient in treating the patient and have reduced adverse effects on the patient to enhance patient comfort during treatment. Cho et al. discloses, on page 6, paragraph 50, the present invention treats sleep apnea without waking the patient and thus provides them with a more restful sleep. This is an example of reducing the adverse effects on the patient while enhancing the efficiently without compromising the treatment.

2. Claims 1-9, 14-18, 22-27, 30-34, 37, 39-48, 80-83, 85-86, 88-96 and 98-100 are rejected under 35 U.S.C. 102(e) as being anticipated Park et al. (US 6,928,324). Park et al. discloses a stimulation device for sleep apnea prevention, detection and treatment.

"In addition to preventing sleep apnea, the cardiac stimulation device 100 may detect episodes of sleep apnea using the physiological sensor 102 and invoke a treatment for sleep apnea. One sleep apnea treatment involves pacing the heart at a rate that is at least partly dependent on information from the metabolic demand sensor and the activity sensor"(col. 6, lines 40-43). "Suitable metabolic demand parameters for controlling prevention and treatment of the pacing rate include the QT interval, respiration rate, venous oxygen saturation, stroke volume, venous blood temperature, respiration including rate, amplitude, and minute volume, and others"(col. 4, lines 32-36).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 19-21, 35-36, 38, 84 and 97 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cho et al. (US Patent Publication 20020193697 A1) or Park et al. (US 6,928,324). Cho et al. and Park et al. disclose the claimed invention except for the external sensor. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the implantable sensor as taught by Cho et al. and Park et al. with an external sensor since it was known in the art to utilize external sensor, which are less invasive to the patient.

As to claims 35-36 and 38, Cho et al. and Park et al. disclose the claimed invention except for the estimated accuracy or sensitivity. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the criteria as taught by Cho et al. and Park et al. with a estimated accuracy or sensitivity since it was known in the art to include a factor of safety or utilize calculations of accuracy, such as standard deviations in order to determine relevant data and prevent outliers.

As to claim 97, Cho et al. and Park et al. disclose the claimed invention except for the operation to conserve the life of the IMD. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the operations of the apparatus as taught by Cho et al. and Park et al. with power conserving operations since it was known in the art that power conserving operations enable the life of the IMD, specifically battery life, to be prolonged and thus reduce the maintenance needed by the IMD.

As to claims 19-21, Cho et al. and Park et al. disclose the claimed invention except for the time interval. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the time interval, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller,* 105 USPQ 233 (see MPEP 2144.05).

2. Claims 10-13 and 87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cho et al. (US Patent Publication 20020193697 A1), or Park et al. (US 6,928,324),

in view of Bardy (US 6,398,728 B1). Cho et al. and Park et al. disclose the claimed invention except for the non-physiological and medical history. Bardy teaches that it is known to input medical history and monitor environmental factors as set forth in column 1, lines 33-43, since both factors affect respiratory disease. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the detected data as taught by Cho et al. and Park et al. with the detected data as taught by Bardy, in order to modify treatment to meet specific patient needs.

3. Claims 43-44, 46 and 99 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cho et al. (US Patent Publication 20020193697 A1) in view of Sweeney et al. (US 6,272,377). Cho et al. discloses the claimed invention except for the ventricular pacing, multi-chamber pacing and non-excitatory pacing. Sweeney et al. teaches that it is known to modify the pacing therapy as set forth in column 8, lines 19-22. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the pacing therapy as taught by Cho et al. with the variety of pacing therapy as taught by Sweeney et al., since such a modification would modify the pacing therapy to meet specific patients needs.

Specification

1. The disclosure is objected to because of the following informalities: Serial Numbers are missing from commonly owned patents in the following paragraphs: 41, 42, 45, 140 and 193. Appropriate correction is required.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

1. Barker (US 4,365,636) discloses a method and process for the analysis of respiration signals for the purpose of detecting and predicting apnea.

2. Bonnet (US 6,574,507) discloses a device that responds to sleep apnea syndrome.

3. Poezevara (US 20040176695 A1) discloses an implantable medical device, specifically cardiac pacemakers, for the detection of sleep disorders.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alyssa M. Alter whose telephone number is (571) 272-4939. The examiner can normally be reached on M-F 9am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Alyssa M. Alter

Alyssa M Alter
Examiner
Art Unit 3762

AA

JEFFREY R. JASTRZAB
PRIMARY EXAMINER

11/7/05